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K014025
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510(k) Summary

HomMed Sentry III Patient Monitor System

Contact: Herschel Peddicord, President
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Trade Name: HomMed Sentry III Patient Monitor System with Card Reader

Common Name: Patient Vital Signs Monitor with Card Reader

Classification Name: Oximeter

Substantial Equivalence is Claimed to:
HomMed Sentry III Patient Monitor System

Device Description: The HomMed Sentry III Patient Monitor System with Card Reader is a portable patient vital signs monitoring system which allows patients to use multiple Sentry III monitors or multiple patients to use the same Sentry III monitor. The system measures noninvasive blood pressure, pulse rate, oral temperature, oximetry, and weight. In addition, the system has optional glucometry and spirometer measuring capabilities. The Sentry III Patient Monitor with Card Reader acquires the patient vital signs data and displays it. The data can also be transmitted via the communication system through the Skytel Pager Network to a central station for storage with retrospective display and analysis. The Card Reader with the HomMed Sentry III Patient Monitor System allows patients to use multiple monitors or multiple patients to use the same Sentry III monitor.

Indications for Use: The HomMed Sentry III Patient Monitor System with Card Reader is intended for in home and/or healthcare facility applications under physician orders. The Card Reader with the HomMed Sentry III Patient Monitor System allows patients to use multiple Sentry III monitors or multiple patients to use the same Sentry III monitor. The use of the system is to allow retrospective review of certain patient physiological functions. The HomMed Sentry III Patient Monitor System with Card Reader can measure and display patient data including noninvasive blood pressure, pulse rate, oral temperature, oximetry, and weight. Additionally, the patient vital signs data can be communicated to a central review station via a pager network with a backup landline telephone modem for telephone communication with the central pager network if necessary.

The HomMed Sentry III Patient Monitor System with Card Reader provides a noninvasive blood pressure (NIBP) monitor for measurements of a patient's systolic, diastolic, and mean arterial (MAP) blood pressures; pulse oximeter, acquires a pulse rate using an oximeter; oral temperature via an electronic thermometer; weight from an electronic scale. All data collected from these functions as well as optional glucometry and spirometry is sent through an internal communication module.

The device will provide fast, reliable measurements on patients ranging from children (pediatrics) to adults when using the appropriate blood pressure cuff. The pulse oximetry works with Sentry III Patient Monitor System pulse oximetry probes provided by HomMed, providing Sp02 and pulse rate on all patients from pediatric to adult. The electronic thermometry requires use of the Welch Allyn oral thermometry probe and probe covers. It provides only oral temperature information. The device is intended for use in the patient home and/or clinical environments by the patient as prescribed by or on orders by a physician with the information transmitted to a central viewing station where healthcare professionals can review the data.

Comparison with Predicate Devices:

This HomMed Sentry III Patient Monitor System allows uncomplicated measurement and remote monitoring of patient vital signs including weight utilizing the existing technologies of the predicate device, HomMed Sentry III Patient Monitor System.

Determination of Substantial Equivalence:

The performance of each component of the HomMed Sentry III Patient Monitor System with Card Reader has been confirmed to be equivalent to the predicate device HomMed Sentry III Patient Monitor System. In addition, the HomMed device continues to utilize an external medical grade power supply ensuring the continued protection and safety for the patient vital signs monitor, scale, and card reader and communication module.

Compliance to Standards and Regulations:

The HomMed Model Sentry III Patient Monitor System with Card Reader complies with the following national and international standards:

Safety	EN 60601-1	Medical Electrical Safety
	IEC 601-1-2	EMC Compliance
	ISO 10993-5,10-11	Biocompatibility

Performance Data:

The HomMed Sentry III Patient Monitor System with Card Reader utilizes the HomMed Sentry III Patient Monitor System within the environments for which Sentry III is marketed. The Sentry III Patient Monitor System with Card Reader performs consistent with guidelines and standards found in the FDA reviewer's guides for respiratory devices and electronic thermometers. EMC, electrical, mechanical durability, safety (operator and patient), and temperature/humidity testing has been completed demonstrating compliance with applicable standards. The test results demonstrated that the Sentry III System with Card Reader is in compliance with the guidelines and standards referenced in the FDA reviewer's guides and that it performed within its specifications and functional requirements.

The HomMed Sentry III Patient Monitor System performance is consistent with the HomMed Sentry III System performance and additional testing has been done on the HomMed Sentry III Patient Monitor System with Card Reader assuring compliance with applicable electrical, safety and healthcare standards. Thus it is the HomMed position that the HomMed Sentry III Patient Monitor System with Card Reader performs as well as the legally marketed predicate device.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of FDA regarding patient monitors.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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HomMed, LLC
c/o Tommie J. Morgan, Ph.D.
President
Morgan Consultants, Inc.
2018 North Durham Drive
Houston, TX 77008

Re: K014025
Trade Name: HomMed Sentry III Patient Monitor System with Card Reader
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II (two)
Product Code: DQA
Dated: March 6, 2002
Received: March 8, 2002

Dear Dr. Morgan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K014025

510(k) Number (if known): K014025

Device Name: HomMed Sentry III Patient Monitor System with Card Reader

Indications for Use

The HomMed Sentry III Patient Monitor System with Card Reader is designed to measure Patient Vital Signs in the home by patients or in clinical environments by health care providers. The HomMed Sentry III Patient Monitor System with Card Reader is available with physicians' orders only. The HomMed Sentry III Patient Monitor System with Card Reader allows patients to use multiple Sentry III monitors or multiple patients to use the same Sentry III monitor.

The HomMed Sentry III Patient Monitor System with Card Reader measures the following parameters: Non-Invasive Blood Pressures (Systolic, Diastolic and Mean Arterial Pressure), Functional Oxygen Saturation (%SpO2), Peripheral Pulse Rate (PPR), Pulse Strength, Oral Temperature and Patient Weight via an external scale. The HomMed Sentry III Patient Monitor System with Card Reader's optional, compatible devices extends those measurements to glucometer and spirometer monitoring. The patient parameter data is collected and displayed by the HomMed Sentry III Patient Monitor System with Card Reader. Data can be transmitted via the communication module to a central station where the patient data can be viewed and analyzed.

(PLEASE DO NOT WRITE BELOW THIS LINE - - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K014025

Prescription Use X OR Over-the-Counter Use _____
Per 21 CFR 801.109)